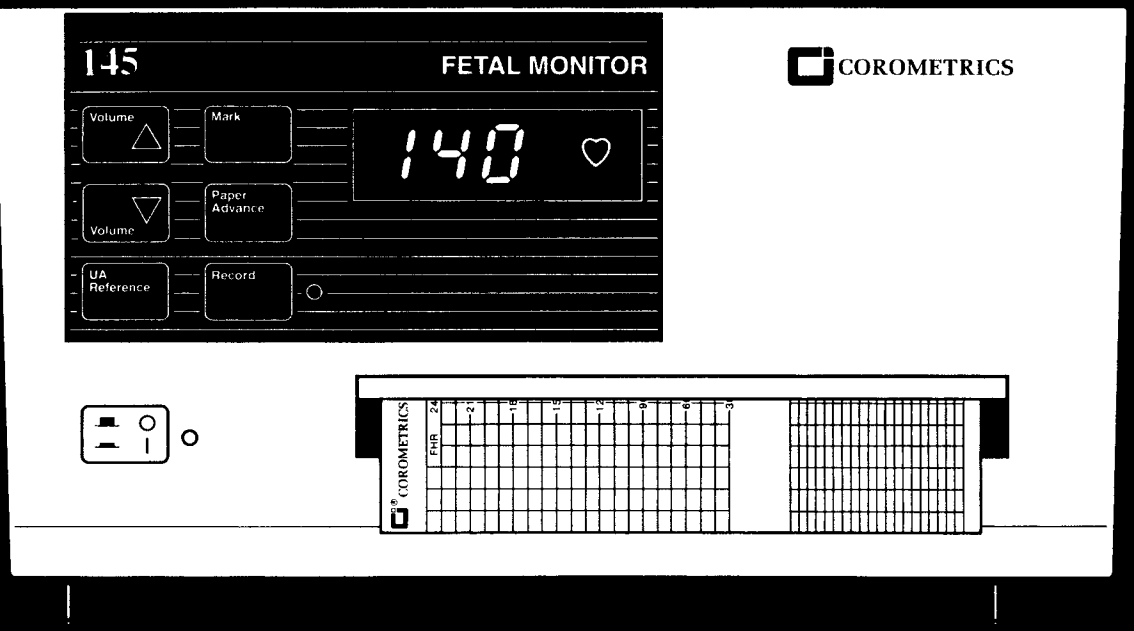
Model 145

FETAL MONITOR

OPERATOR'S MANUAL P/N 1133AA-08



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MEDICAL SYSTEMS, INC.

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SERVICE DEPARTMENT

24-Hour Toll-Free Service
For Corometrics Factory Repair Service, Call 1-800-243-3952
In Connecticut, Call Collect 265-5631

⚠ **CAUTION:** Federal law restricts this device to sale by or on the order of a physician. The Model 145 is not intended for home use.

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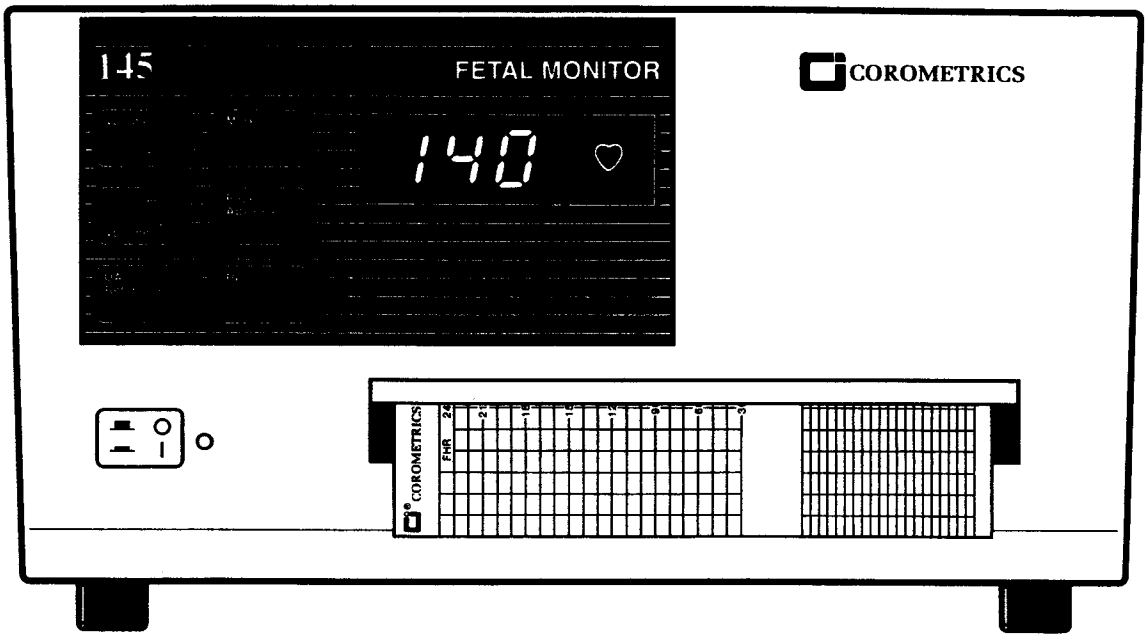


FEATURES

- Cleaner more accurate traces with fewer "dropouts" using ultrasound because of patented autocorrelation processing.
- Quiet, easy-to-load recorder with high-resolution dot matrix printhead. Prints out both trend curves and alphanumeric data on one strip chart.
- Easy-to-use durable transducer connectors.
- All functions controlled by pushbuttons—including audio volume, UA reference, time/date set, and paper advance.

INTRODUCTION

The Corometrics Model 145 Fetal Monitor is designed for fetal heart rate and maternal uterine contraction monitoring using external methods. Simultaneous trends of fetal heart rate (FHR) and uterine activity (UA) are plotted continuously on the built-in dual channel strip chart recorder. FHR is displayed continuously on the front-panel numeric display.

EXTERNAL MONITORING MODES

1. **Continuous-Wave Doppler Ultrasound:** A transducer placed on the abdomen is used to direct an ultrasonic beam toward the fetal heart and to sense Doppler-shifted echoes created by moving cardiac structures. A patented autocorrelation process is used to determine the timing of successive cardiac cycles.

2. **Tocodynamometer:** A tocotransducer placed on the maternal abdomen will record changes in abdominal tension. The resulting tracings will reflect uterine contractions or fetal movement. The readings are recorded on the strip-chart paper in a relative scale from 0 to 100.

⚠ SAFETY INFORMATION

The **DANGERS, WARNINGS** and **CAUTIONS** that appear throughout this manual are not only preventative measures designed to uphold the safety of both patient and operator, but also enhance equipment reliability. The definitions of **DANGER, WARNING** and **CAUTION** in this manual comply with ANSI Z535.2, American National Standard for Environmental and Facility Safety Signs, and ANSI Z535.4, Product Safety Signs and Labels, issued by the American National Standards Institute.

⚠ **DANGER** indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠ **WARNING** indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ **CAUTION** indicates a hazardous situation which, if not avoided, may result in minor or moderate injury.

⚠ **IMPORTANT** indicates an *emphasized* note. It is something you should be particularly aware of; something not readily apparent.

DEFINITION OF SYMBOLS

⚠ This symbol complies with IEC 601.1, and is described in IEC publication 348. The symbol prescribes the following information to the equipment user: **ATTENTION, CONSULT ACCOMPANYING DOCUMENTS**

IPX1 This symbol complies with IEC 601.1, and is described in IEC publication 529. The symbol prescribes the following information to the equipment user: **DRIP-PROOF**

⏚ This symbol complies with IEC 601.1, and is described in IEC publication 417-5021. The symbol prescribes the following information to the equipment user: **EQUIPOTENTIALITY**

0 This symbol complies with IEC 601.1. The symbol indicates the power is **OFF**.

I This symbol complies with IEC 601.1. The symbol indicates the power is **ON**.

GENERAL USE

⚠ **DANGER:** Do not use this equipment in the presence of flammable anesthetics or inside an oxygen tent. Such use would present an explosion hazard.

Read this manual before operating the Model 145 Fetal Monitor. Keep this manual available for future reference and for the orientation of new personnel.

Refer to the supplementary Guide to Fetal Heart Rate Monitoring for information concerning the limitations of internal and external fetal heart rate monitoring techniques.

It is recommended that this equipment be plugged into the same AC power circuit accommodating other equipment being used on a specific patient.

The equipment should be kept clean, dry, and free of transducer gel and other substances.

Direct monitoring should be used only under aseptic conditions.

Do not operate the unit if it is damp or wet due to condensation or spills. Avoid moving the equipment from a cold environment to a warm humid location. If the equipment is brought inside from outdoors, and is cold to the touch or below room temperature, allow the unit to stabilize at room temperature before operating.

Use only Corometrics approved transducers with the monitor.

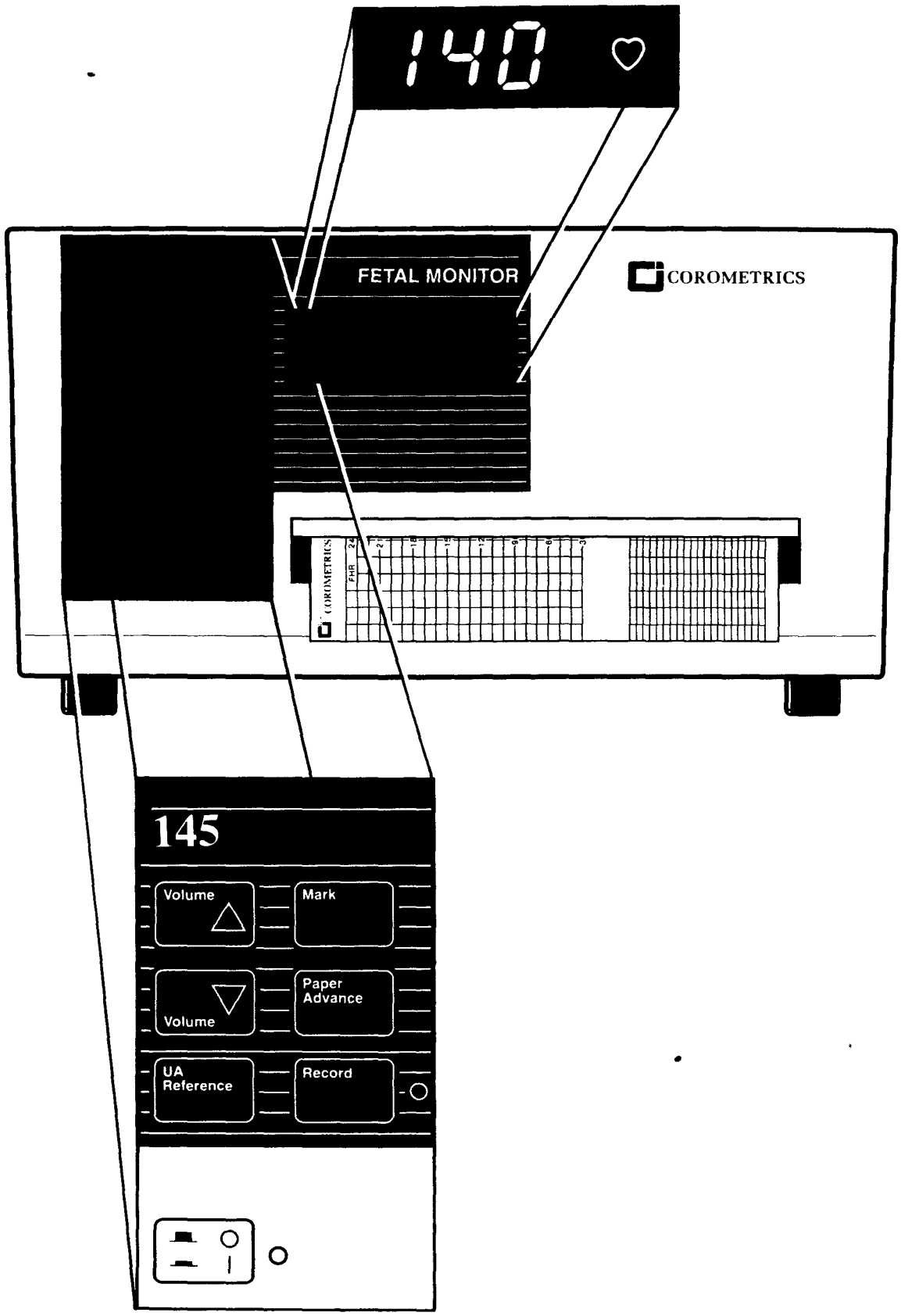
SAFETY PRECAUTIONS

Domestic (U.S.A.) equipment models are manufactured to operate from a hospital grade three-wire 120 volt AC electrical outlet. Corometrics recommends the use of dedicated AC power lines. The equipment can be modified to accept other AC line voltages and outlet types; however, only those personnel designated by Corometrics Medical Systems, Inc. are authorized to make such modifications.

> ⚠ **WARNING:** Do not use adaptors or make AC plug modifications. Such changes could defeat the three-wire safety ground of the AC power cord and result in a dangerous electrical shock hazard to both operator and patient.

LEAKAGE CURRENT

Corometrics Fetal Monitors are designed to comply with Underwriters Laboratory (UL 544), CSA, IEC, and TUV standards for leakage current in patient connected medical equipment. The system's ultrasound and tocotransducers are electrically isolated, and leakage current is limited to a few microamperes even when full power line voltage is applied to these devices. However, for maximum patient safety, a leakage test should be conducted following any repair or servicing of the monitor. When conducting a leakage test, conform to the UL 544 standards or similar ones such as the AAMI Safe Current Limits Standard on Leakage Current.


140
FETAL MONITOR
COROMETRICS
145
Volume
Mark
Volume
Paper Advance
UA Reference
Record

CONTROLS AND INDICATORS

FRONT PANEL DISPLAYS

Heart Rate Display

Heart rate, in beats per minute will be displayed in this window.

Heartbeat Indicator

A heart-shaped symbol flashes with each detected valid heartbeat.

FRONT PANEL CONTROLS

Power

Pushbutton that activates the monitor. When depressed, the monitor performs a self test and a green light next to the pushbutton illuminates. The recorder remains active following completion of power up self test.

UA Reference

Pushbutton that sets the pressure level on the UA channel at 10 for the tocodynamometer. To activate, depress and hold for 1 second. The chart paper will automatically be annotated. If pressure falls below 0, automatic UA reference will occur and new baseline reference is set at 0.

In the **SET TIME/DATE** mode the successive depression of the **UA Reference** pushbutton permits selection of the time or date parameter to be changed.

Volume

Two pushbuttons used to change the volume of sound emitted by the speaker. Depressing the button with the arrow pointing down causes the volume to decrease. Depressing the button with the arrow pointing up causes the volume to increase. Volume has no effect on the processing used to compute heart rate.

In the **SET TIME/DATE** mode, the arrows are used to increase or decrease the time/date parameter selected by the **UA Reference** pushbutton.

Mark

When depressed, this pushbutton causes an arrow shaped mark to be printed on the strip chart recorder paper. The Mark pushbutton is typically used to show where a specific event occurred on the strip chart paper.

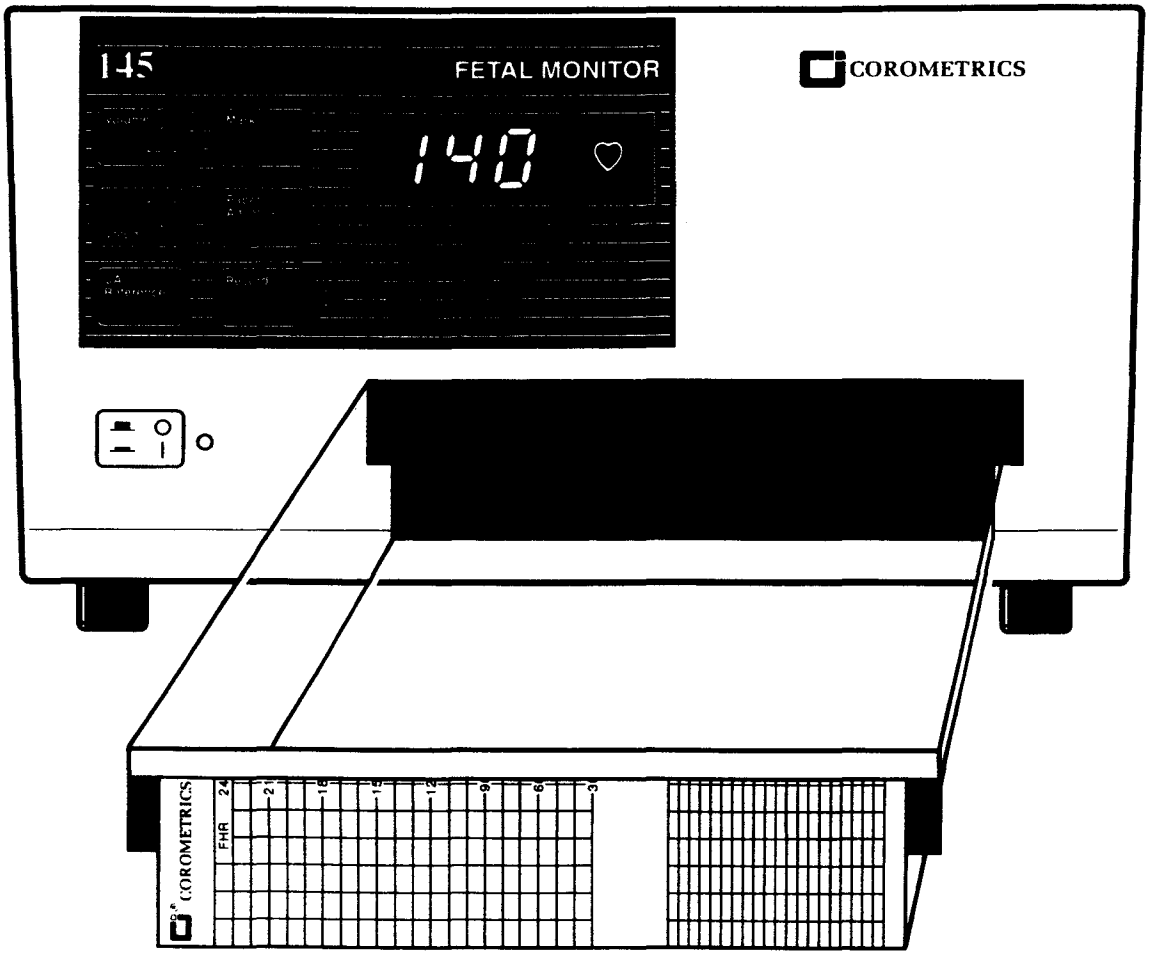
Paper Advance

When depressed, chart paper will advance at a speed of 25 cm/min. The recorder will not print during this time.

Record

When depressed, this pushbutton activates the recorder. Once the recorder is activated, depressing **Record** again turns it off.

A yellow light next to the **Record** pushbutton will be illuminated when the recorder is activated and turned off when the recorder is deactivated.



STRIP CHART RECORDER

The dual-channel strip chart recorder is located on the right side of the front panel.

Heart Rate Channel

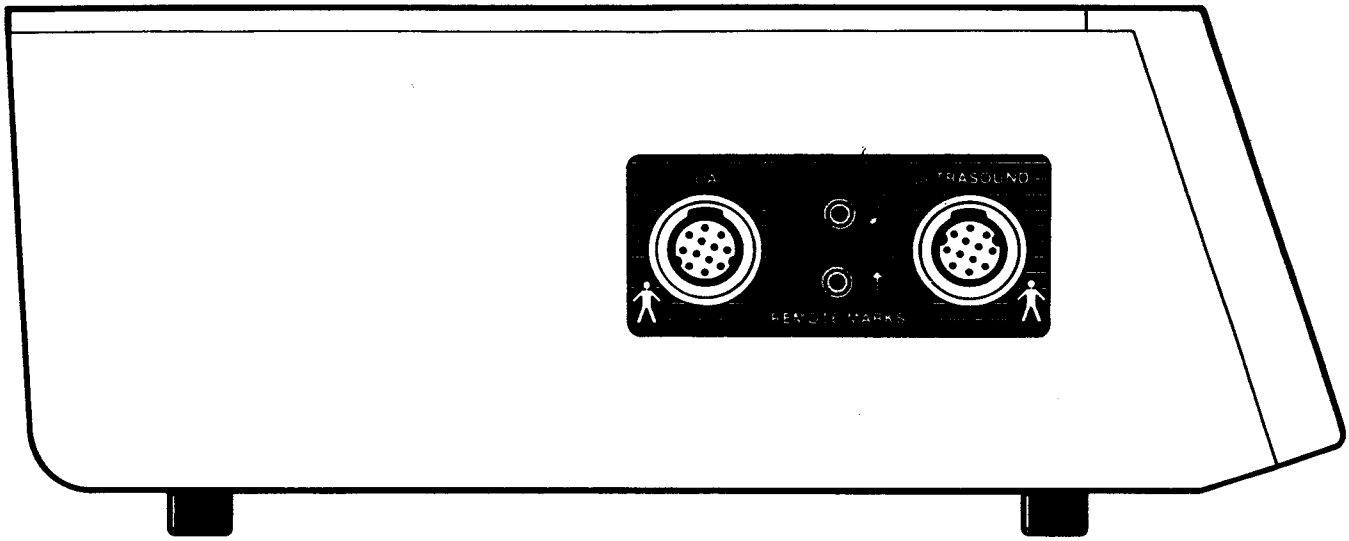
The heart rate channel is located on the left side of the recorder.

Uterine Activity Channel

The uterine activity channel is located on the right side of the recorder.

Alphanumeric Print-Out

When the recorder is activated, time and date are printed automatically on the margin between the heart rate and uterine activity channels.



LEFT SIDE PANEL CONNECTORS

Ultrasound

Ocher colored 12-pin connector mechanically keyed to accept only the Model 145 ultrasound transducer plugs.

UA

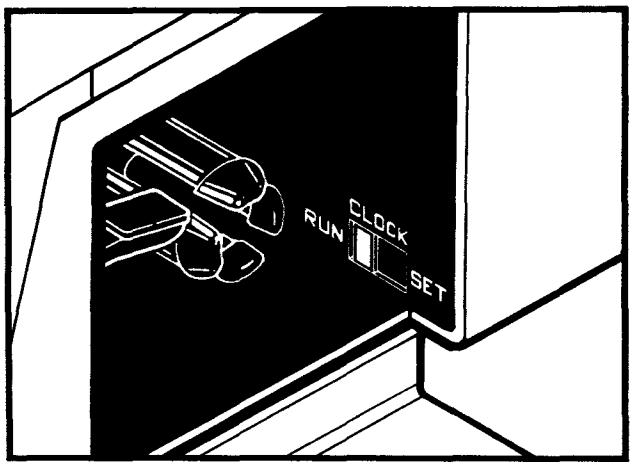
White 12-pin connector which is mechanically keyed to accept the tocotransducer.

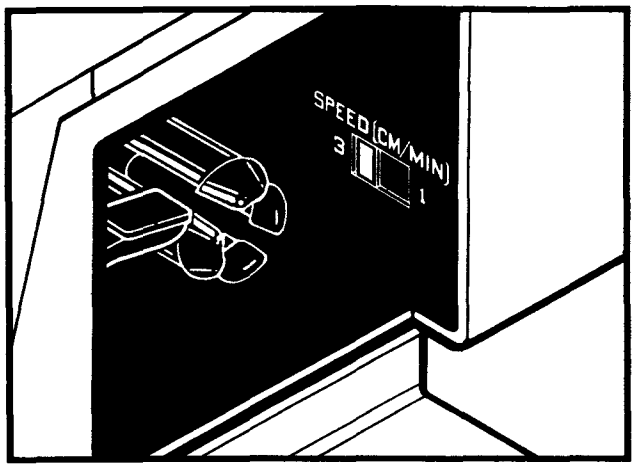
Remote Mark (↑)

Input for remote pushbutton to perform the **Mark** function. When activated, an arrow with FM will be printed on the chart paper.

Fetal Acoustic Stimulator Mark (♪)

Input connector for Corometrics Model 146 Fetal Acoustic Stimulator. When the 146 is activated, a musical note symbol is printed on the strip chart recorder paper.





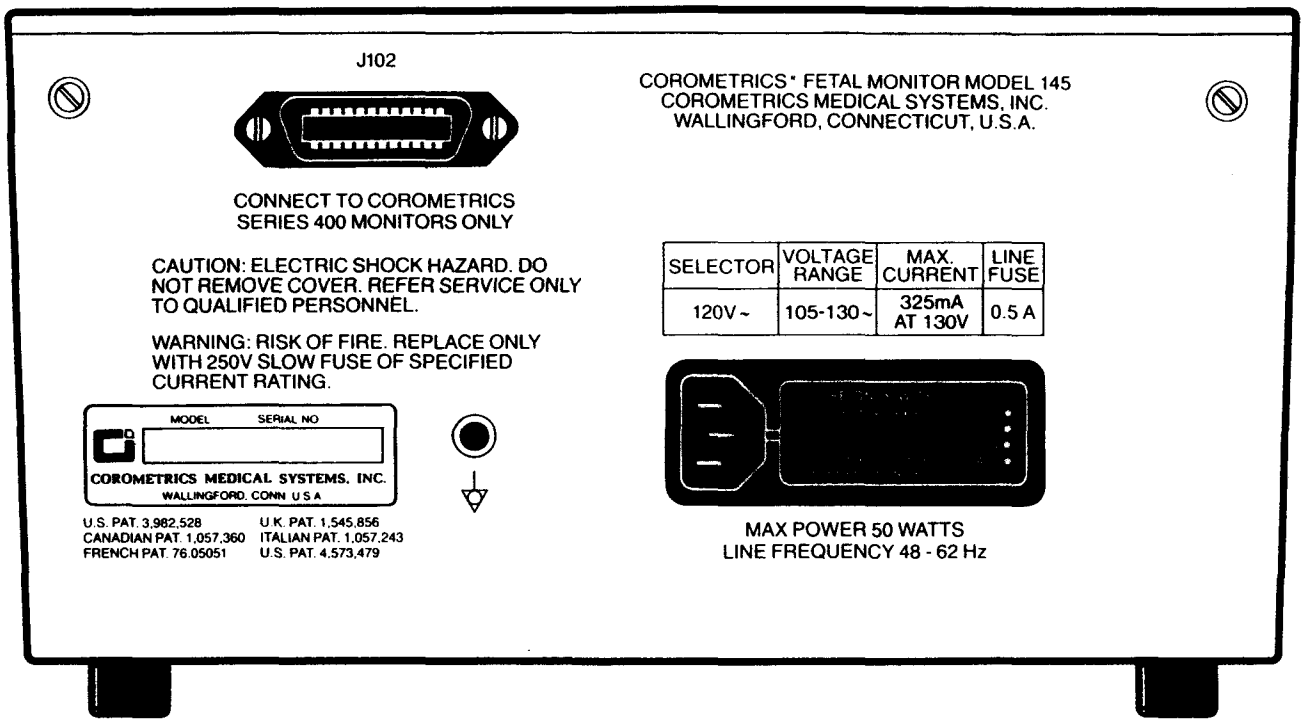
RIGHT SIDE PANEL (Behind Door)

Speed Select Switch

Switch (top) located on the bottom right hand corner of the recorder. Pushed toward the inside of the monitor, the recorder speed is set to 3 cm/min. Pushed toward the outside of the monitor, the recorder speed is set to 1 cm/min.

Set Time and Date Switch

Switch (bottom) located on the bottom right hand corner of the recorder. Pushed toward the inside of the monitor, the clock will maintain normal time. Pushed toward the outside of the monitor, the time and date can be set.



REAR PANEL

Ground Lug

Terminal which can be used to provide an auxiliary ground for the monitor.

J101 Connector

AC line-cord connector.

J102 Connector

Connector for use with Corometrics SPECTRA 400.

Monitor Fuses

Refer to rear panel chart.

OPERATION

FETAL HEART RATE MONITORING

EXTERNAL METHOD

Ultrasound

An ultrasound transducer placed on the maternal abdomen senses heart motion utilizing the Doppler principle. The rate is determined using the patented autocorrelation processing to determine the time interval between successive heart beats.

Fetal Heart Rate Displays

The fetal heart rate is displayed in several ways. A heart beat indicator (amber backlit heart symbol) flashes for each detected valid heart beat. It does not flash for event triggers which are rejected by the monitor's editing. A three digit amber numeric display indicates FHR in beats per minute. This display will be blanked (- - -) if a front panel FHR connector is not inserted into the monitor. FHR trends will be plotted on the fetal channel of the strip chart. There is a few seconds delay from printing until the tracing appears on the moving chart paper. The rear panel speaker will emit audible tones which reflect the Doppler shift signals sensed by the monitor.

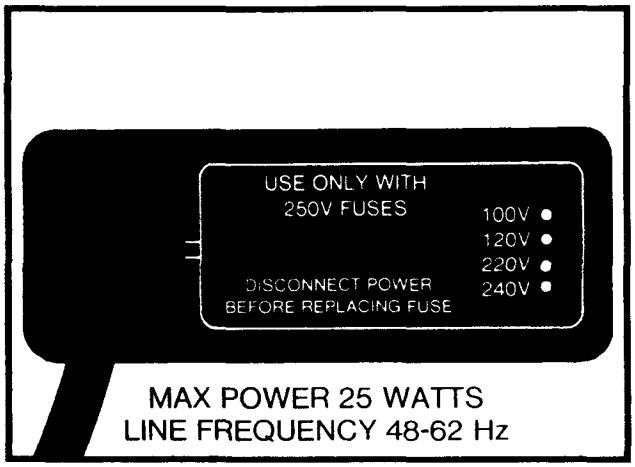
UTERINE ACTIVITY

Tocodynamometer

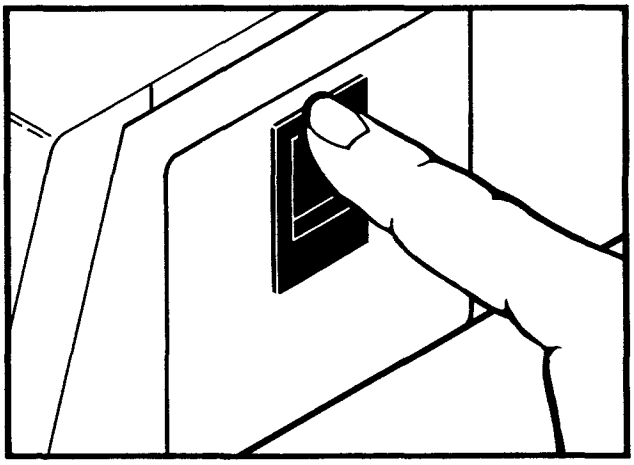
A tocotransducer placed on the maternal abdomen will record changes in abdominal tension. The resulting tracings will reflect uterine contractions and fetal or maternal movement.

PREPARATION FOR USE

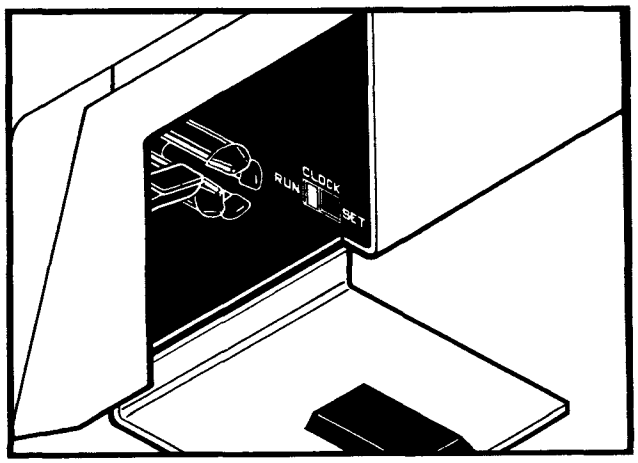
1. Plug the power cord into the rear panel connector and into a grounded electrical wall outlet.



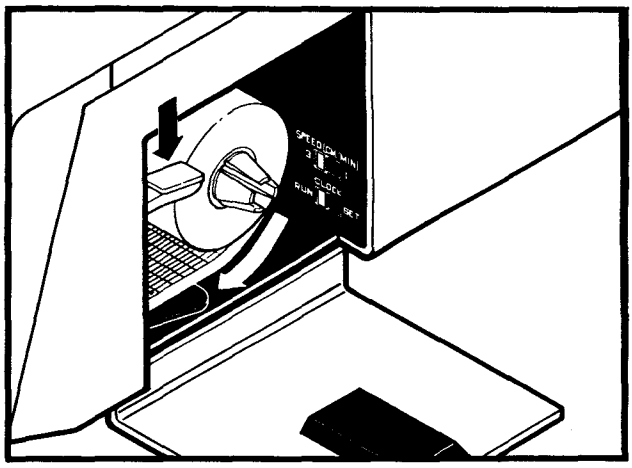
2. Press and release the door located on the right side of the unit.



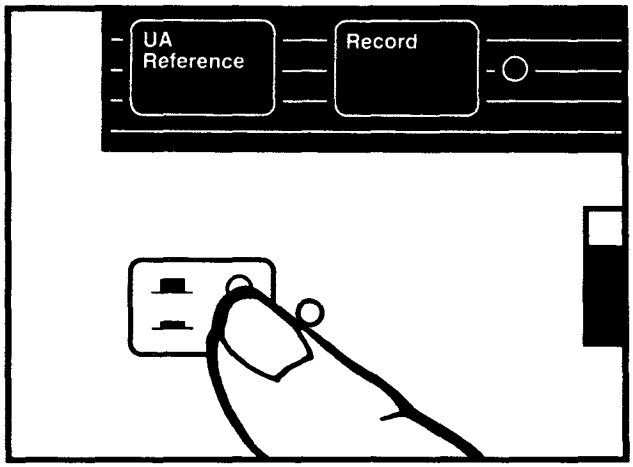
3. Pull the door the rest of the way open. Check that the recorder speed is set to 3 cm/min (speed select switch pushed toward the inside of the monitor).



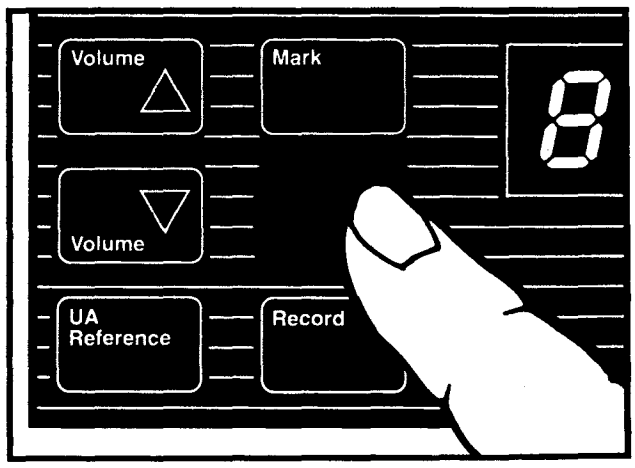
4. Remove the tape holding the paper roll closed. Hold the roll so that the leading edge feeds from the bottom and towards the front of the instrument. Depress and hold the paper-loading lever and continue to advance the paper through the recorder assembly. Release the paper-loading lever.



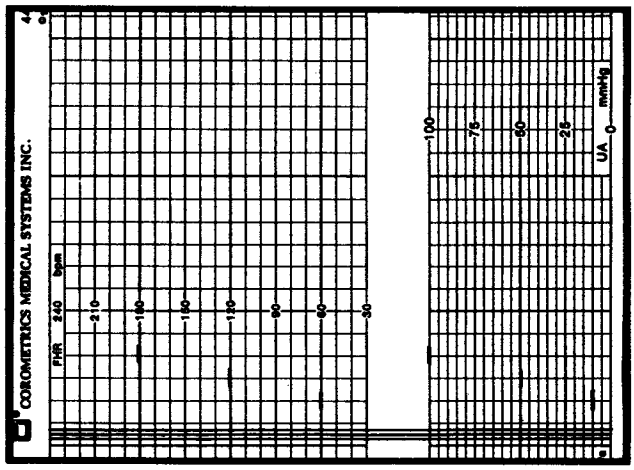
5. Depress the **Power** pushbutton.



6. Depress the **Paper Advance** pushbutton.



7. The Model 145 contains a test routine which checks the calibration and internal circuitry of the monitor. When the **Power** pushbutton is depressed, the following will occur:



A) The green "power on" indicator will be lit.

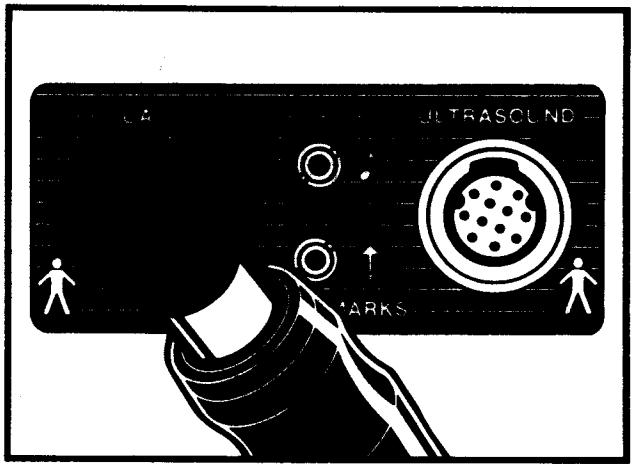
B) The paper will advance at 25 cm/min.

C) The front panel heart rate numeric display will sequence through "111" to "999".

D) Three continuous lines will be drawn across the paper to insure that all the dots in the printhead are functional.

E) Six horizontal lines at 60, 120, 180 bpm and 10, 50 and 100 are then drawn to check the calibration of the recorder.

8. Connect the appropriate transducer plug to the corresponding color-coded connector on the side panel of the monitor.



APPLICATION OF MONITOR TO PATIENT

FHR RECORDING—ULTRASOUND

Equipment Needed

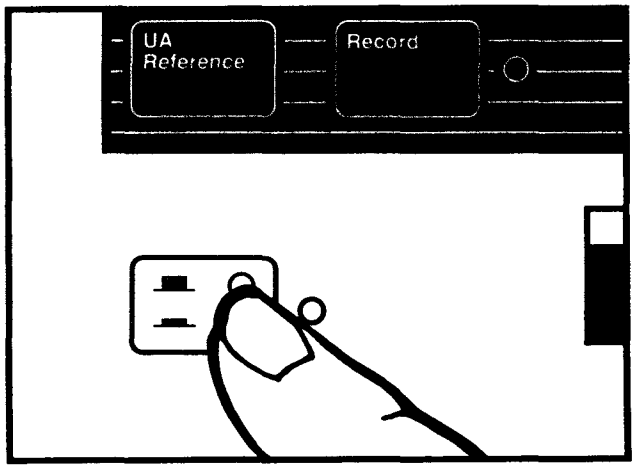
A) Ultrasound Transducer

B) Ultrasound Strap (disposable or reusable)

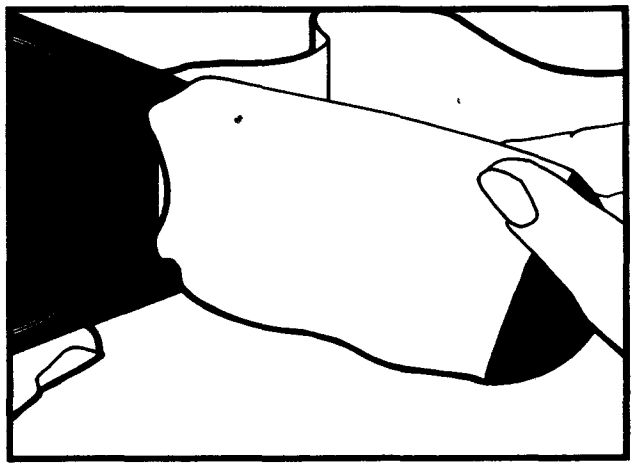
C) Ultrasonic Coupling Gel

Procedure

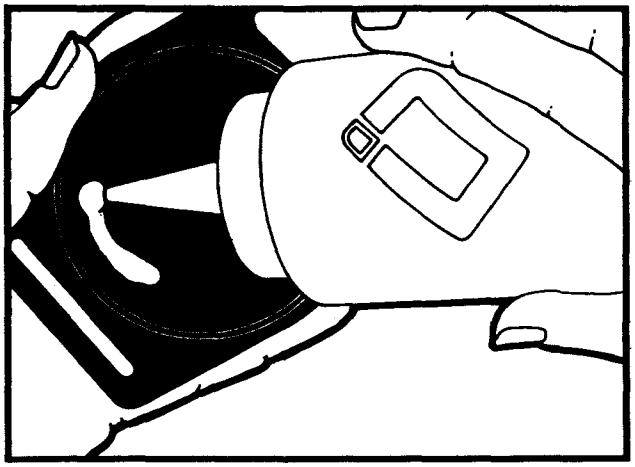
1. Explain procedure to patient.
2. Place strap under patient.
3. Determine position of the fetus using Leopold's maneuvers.
4. Depress "Power" pushbutton if power is off.



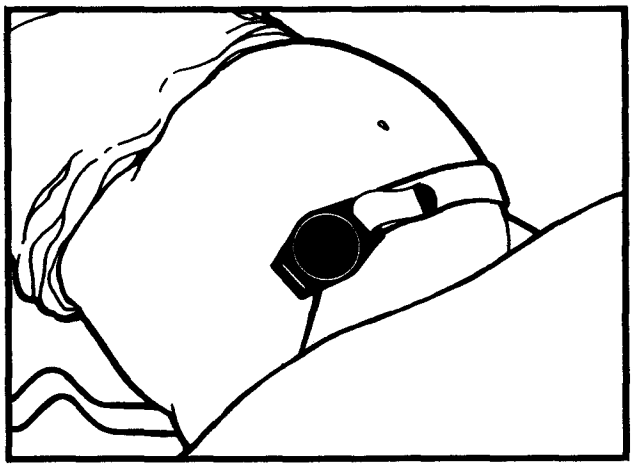
5. Insert a corner of the strap through one slot on the transducer and pull it through several inches.



6. Apply a small amount of ultrasonic coupling gel to the transducer face.

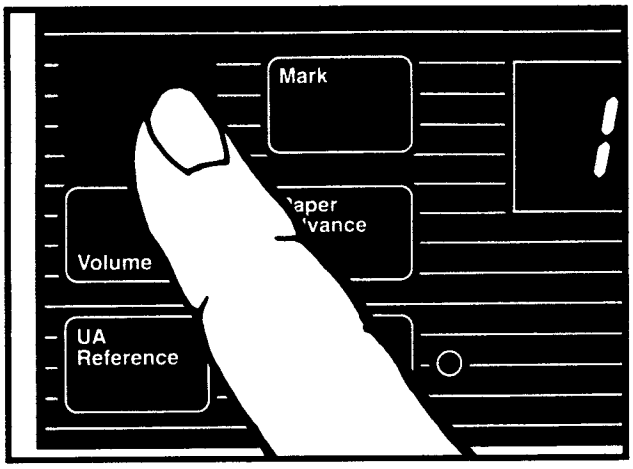


7. Place the transducer face down on the maternal abdomen where the strongest heart tones are heard.

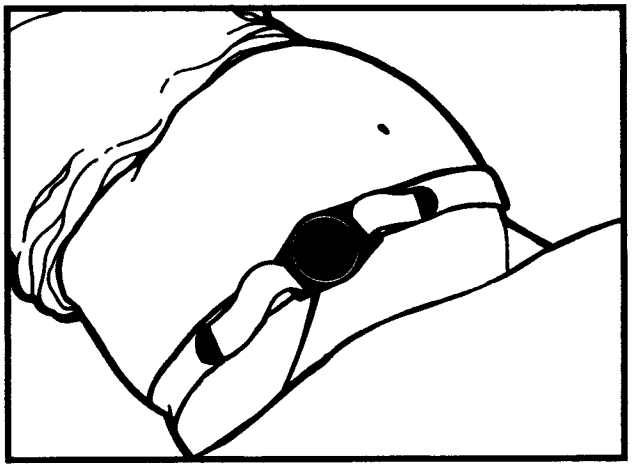


8. Adjust volume on front panel of monitor.

9. Reposition transducer as necessary until clearest heart sound is heard through the speaker.

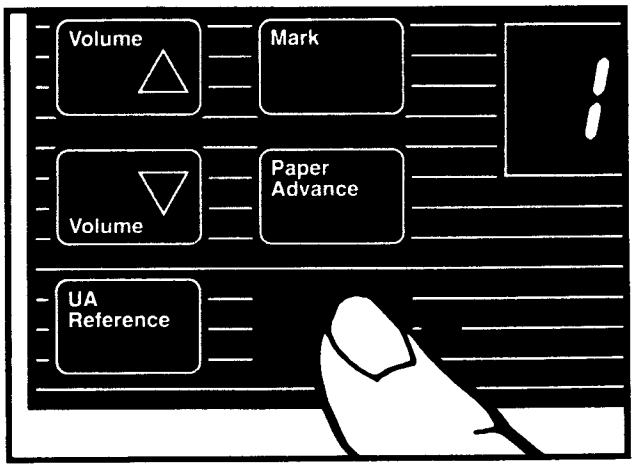


10. Insert the other end of the strap through the remaining slot in the transducer and adjust to a comfortable fit. Three to five seconds after a clear heart sound is heard, the heart shaped indicator will flash synchronously with the sound, indicating signal acceptance and recording.



11. Activate the recorder and insure that a tracing appears on the heart rate channel. Check to make sure the heart rate is fetal and not the maternal pulse.

NOTE: Temporary loss of signal will cause the heart light to stop flashing. If sound is still clear, allow 3 to 5 seconds for light to resume flashing. Fetal movement or maternal movement which results in loss of sound for an extended period may require repositioning the transducer.



UTERINE ACTIVITY RECORDING— TOCODYNAMOMETER

Equipment Needed

A) Tocotransducer

B) Strap (Reusable or disposable)

Procedure

1. Explain monitoring procedure to patient.

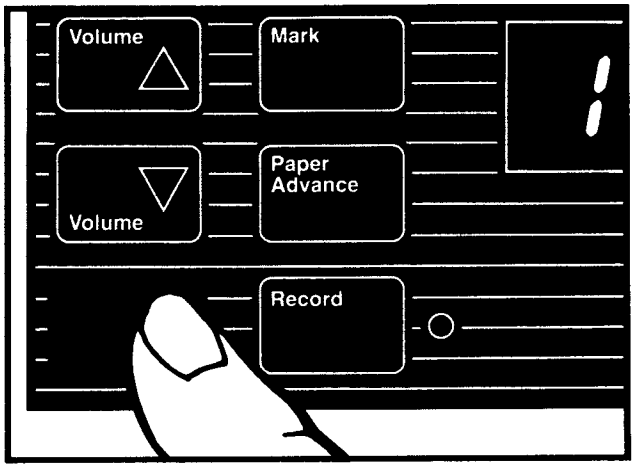
2. Place strap under patient.

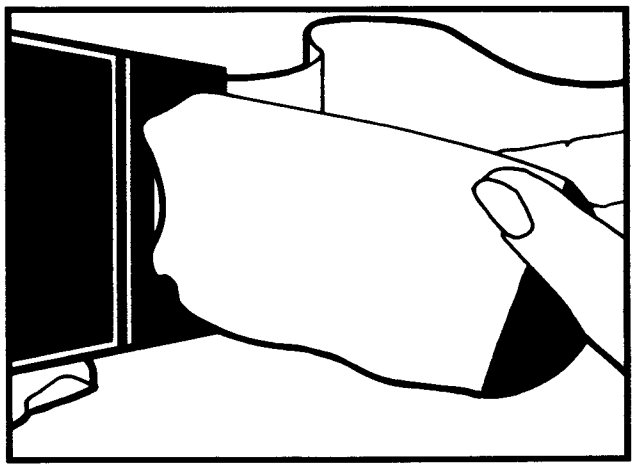
3. Connect the transducer cable to the side panel UA connector. Depress **POWER** and **RECORD** pushbuttons if off.

4. Depress **UA Reference** pushbutton for 1 second. (Count "one, one thousand").

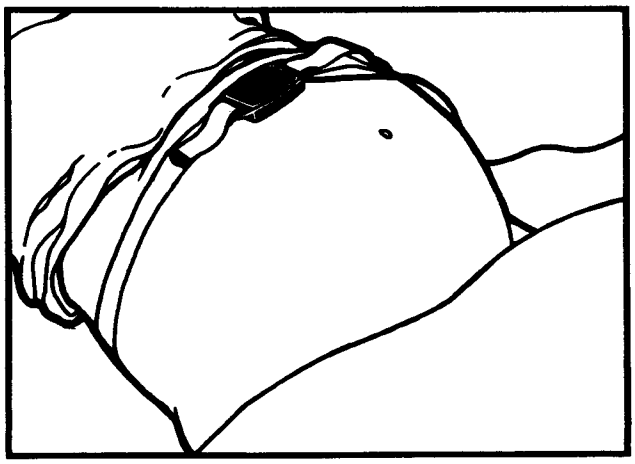
5. Insert the strap through one slot of the tocotransducer.

6. Place the transducer on the maternal abdomen over the uterine fundus or where there is the least maternal tissue.

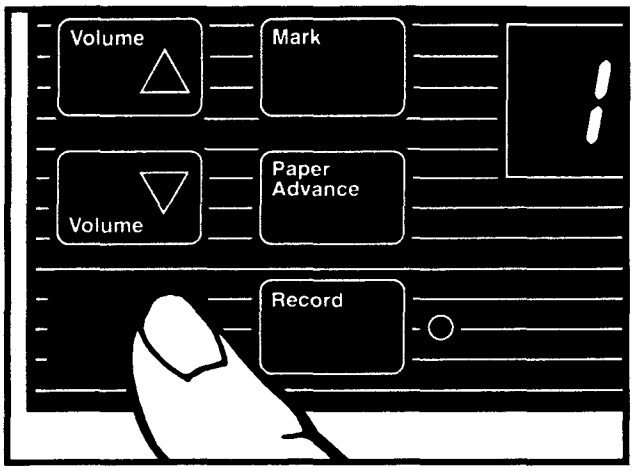




7. Insert the other end of the strap into the remaining slot and tighten sufficiently to hold the transducer securely in place. The tracing on the recorder should plot approximately one third of the way up from the bottom on the **UA** scale (between contractions).



8. When the uterus is at rest, depress the **UA Reference** pushbutton for 1 second. This will reset the UA reference to the 10 unit line. The Model 145 is now ready to begin monitoring uterine activity.



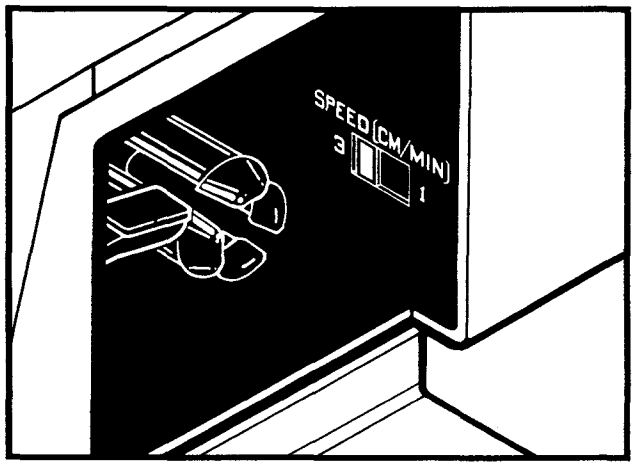
9. To check operation of the system, depress the top of the transducer slightly and verify that there is upward deflection of the reading on the strip chart paper.

Automatic Baseline "Zeroing"

If pressure falls below 0, automatic UA reference will occur and new baseline reference is set at 0. The lower portion of the HR channel will automatically be annotated with "U".

A
↓

SET TIME/DATE

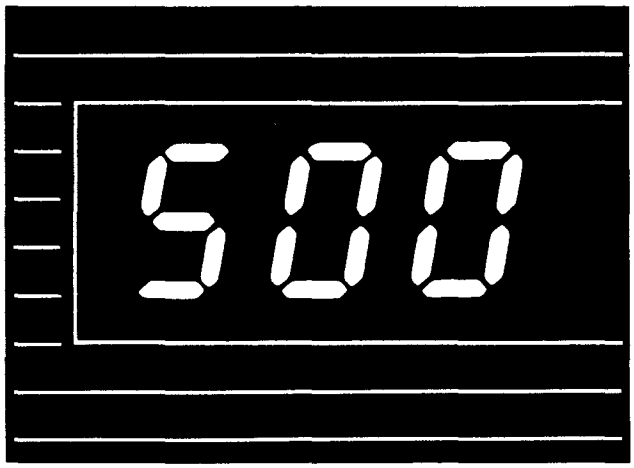


To set minutes, hours, day, month and year push the **Clock** switch located inside the recorder towards the outside of the recorder. (set)

The clock will only need to be set prior to initial operation. A lithium battery keeps the clock running even when the monitor is unplugged for a minimum of 5 years.

UNIT OF TIME	CODE	RANGE
Minutes	5	00 - 59
Hours	6	00 - 23
Day	7	01 - 31
Month	8	01 - 12
Year	9	00 - 99

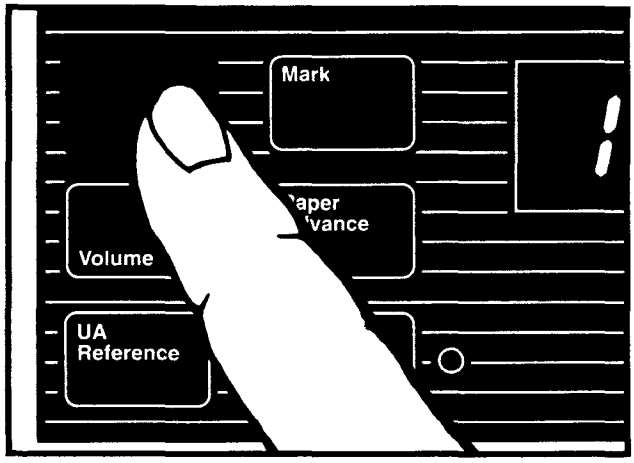
NOTE: If the battery discharges, all ranges will start with "00" during the resetting period.



TO SET MINUTES

Depress the **UA Reference** pushbutton until the numeral "5" (the code for minutes) appears on the left of the numeric display. Any two numbers between the range of 00-59 will appear to the right of the code (5). This is the current time in minutes.

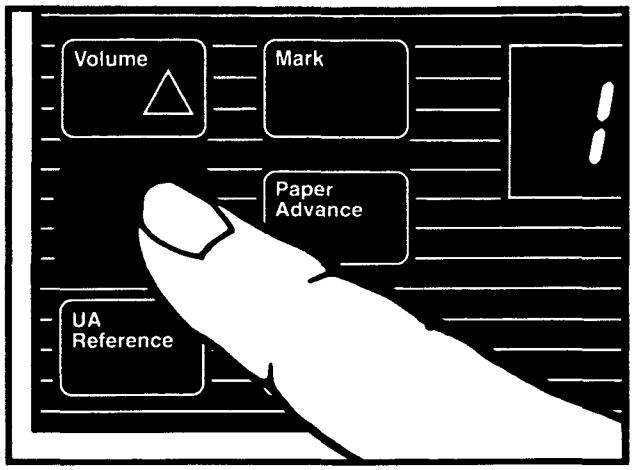
To increase the minutes to the correct setting, depress the **Volume Up** pushbutton. The two numerals on the right of the "5" will increase to the desired setting.



To decrease the minutes to the correct setting, depress the **Volume Down** pushbutton until the two numerals on the right of the "5" decrease to the desired setting.

Continue depressing either the **Volume Up** or the **Volume Down** pushbutton until the correct minutes are set.

NOTE: The numeric increments or decrements are one per second and then the rate increases until the switch is released.

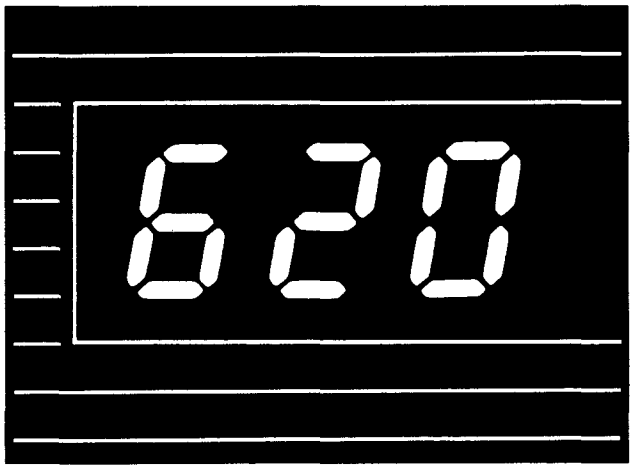


TO SET HOURS

NOTE: The internal clock is a 24 hour clock. One minute past midnight will be printed in military time as 00:01 on the recorder, and 1 minute to midnight will be printed as 23:59. The format is as follows:

HH:MM	Month/Day/Year (Domestic)
HH:MM	Day/Month/Year (Europe)
HH:MM	Year/Month/Day (Japan)

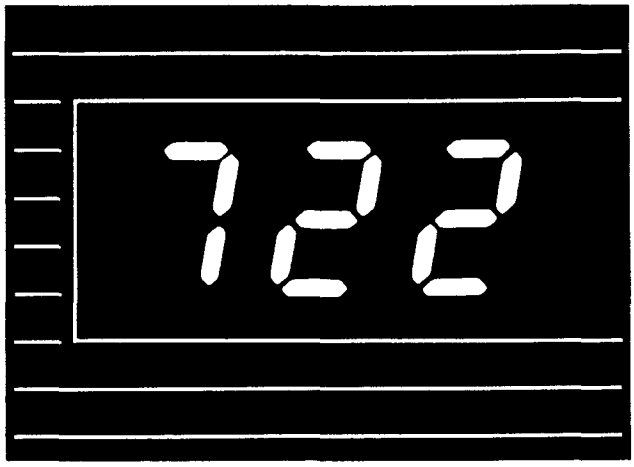
Depress the **UA Reference** pushbutton until the numeral "6" (the code for hours) appears on the left of the numeric display. Any two numbers between the range of 00-23 will appear to the right of the code (6). This is the current time in hours.



Depress either the **Volume Up** or the **Volume Down** pushbutton, to either increase or decrease the two numerals located on the right, to the desired setting.

TO SET DAY

Depress the **UA Reference** pushbutton until the numeral "7" (the code for day) appears on the left of the numeric display. Any two numbers between the range of 01-31 will appear on the right of the code (7). This is the current day.

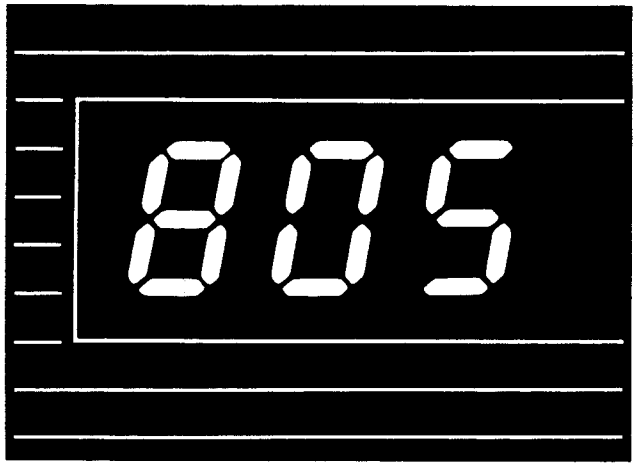


Depress either the **Volume Up** or the **Volume Down** pushbutton, to either increase or decrease the two numerals located on the right, to the desired setting.

TO SET MONTH

Depress the **UA Reference** pushbutton until the numeral "8" (the code for month) appears on the left of the numeric display. Any two numbers between the range of 01-12 will appear on the right of the code (8). This is the current month.

Depress either the **Volume Up** or the **Volume Down** pushbutton, to either increase or decrease the numeric value located on the right, to the desired setting.

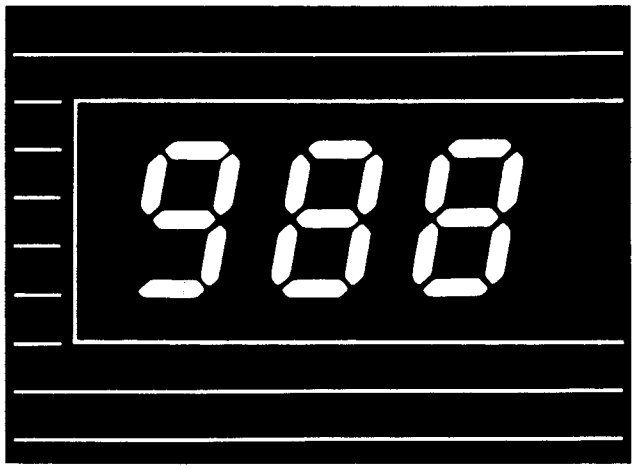


TO SET YEAR

Depress the **UA Reference** pushbutton until the numeral "9" (the code for year) appears on the left of the numeric display. Any two numbers between the range of 00-99 will appear on the right of the code (9). This is the current year.

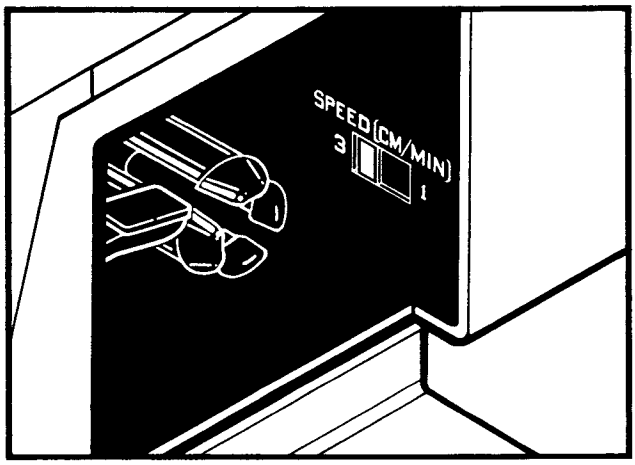
Depress either the **Volume Up** or the **Volume Down** pushbutton, to either increase or decrease the numeric values located on the right, to the desired value.

Recheck the minutes as described previously and reset if necessary.



To return to the normal mode of operation set the **Clock** switch to the run position (towards the inside of the monitor).

NOTE: When the recorder is turned on or a paper advance has occurred, the date and time are printed. The time will continue to be printed every 10 minutes. After midnight the date is again printed. If the clock should fail to keep time, see the Troubleshooting Guide.



MAINTENANCE

CLEANING THE FETAL MONITOR

> ⚠ **CAUTION:** Unplug the monitor form the AC power source and detach all accessories from the monitor. Do not immerse accessories in any liquid. Do not use abrasive cloth or cleaners on monitor or accessories.

Wipe any fluids from the surface of the monitor. Dampen a cloth or paper towel with isopropyl alcohol and rub soiled area until clean.

> ⚠ **CAUTION:** Do not clean the lens that covers the heart rate digital display with isopropyl alcohol; clean the lens with a soft dry cloth.

CLEANING THE ULTRASOUND TRANSDUCER AND TOCOTRANSDUCER

> ⚠ **CAUTION:** Do not immerse transducers or hold under running water. Do not clean transducers with caustic solvents such as disinfectants (e.g. Acetone, Cidex, Virex, etc.); such chemicals may cause deterioration of the membrane.

Dampen a cloth or paper towel in a soapy solution and wring out until slightly wet.

> **NOTE:** Many hospitals choose to use Bleach (sodium hypochlorite). The most common way to use Bleach is 1:10, in water.

> **NOTE:** If these agents are felt to be too caustic, wipe the transducers off again with a warm, moist cloth once they have been appropriately disinfected.

Rub soiled area until clean, taking care not to excessively wet the tocotransducer diaphragm seal or the contact surface of the ultrasound transducer.

Use a damp cloth on contact surface of ultrasound transducer and around the seal of the tocotransducer. Do not use a sharp object which might damage the seal of the tocotransducer.

Dry all accessories with a soft, dry cloth.

TROUBLESHOOTING

PROBLEM	PROBABLE CAUSE	SOLUTION
Monitor connected to AC power, green Power On light does not illuminate upon power switch depression.	Monitor not connected to AC-line receptacle. AC power cord defective. AC outlet defective. Power cord not connected to Model 145.	Connect power cord to receptacle. Replace power cord. Use different outlet. Connect power cord to monitor. Call Biomedical Department or service representative.
"HLP" appears on front panel display.	Monitor fails self test.	Call Biomedical Department or service representative.
Recorder does not function. (Record light off) (Record light on)	Recorder not activated. Recorder out of paper.	Depress **Record** pushbutton. Install chart paper. Call Biomedical Department or service representative.
ULTRASOUND not functioning properly.	Connector not properly connected to monitor. Transducer misplaced. Too little gel applied to transducer. Defective transducer. Active fetus or mother. Fetal arrhythmia, hiccups.	Check that connector is firmly attached to monitor. Reposition transducer. Apply more gel. Replace transducer. Wait before moving transducer, FHR will often return. Use alternate technique. Call Biomedical Department or service representative.
Tocotransducer not recording contractions.	Connector not properly connected to monitor. Transducer not properly placed. Transducer not secured to patient. Defective transducer cable. No maternal contractions. UA Reference range exceeded. Transducer defective.	Check that connector is firmly attached to monitor. Reposition transducer. Secure transducer to patient. Replace transducer. Remove transducer. Depress UA reference button. Re-apply transducer. Depress UA reference button again, between contractions. Replace transducer. Call Biomedical Department or service representative.

PROBLEM	PROBABLE CAUSE	SOLUTION
"500" to "559" appears in LED window.	Clock switch is enabled. (set)	Disable clock switch. (run)
No volume.	Volume control too low. Transducer not connected or loose.	Turn up volume control. Plug in transducer.
No monitoring functions.	Monitor not attached to outlet. Clock switch is enabled.	Check attachment. Disable clock switch.
Time prints 0:00 **SET TIME/DATE**	Clock battery discharged.	Call service representative for user replacement battery.
Incorrect Time and Date		Reset Time/Date.
"XX" printed for Time/Date.	Low battery.	Reset Time/ Date or call service representative for user replacement battery.

SPECIFICATIONS

ULTRASOUND

Technique:	Continuous-wave Doppler with autocorrelation processing
Sampling Frequency:	200 Hz
Sampling Resolution:	4 bits
Dynamic Range:	>50 dB
Transmitter Frequency:	2.3 MHz
Transmitter Power:	<10 mW/cm^2
Heart Rate Counting Range:	30-240 BPM (Domestic) 50-210 BPM (International)
Resolution:	1 BPM
Leakage Current:	<10 µA at 120 VAC (isolated via transducer)

PRESSURE RANGE

Toco:	0-100 Relative units (0-125 grams)
Excitation Voltage:	+4.55 VDC
Input Impedance:	
Differential:	>1 M
Common Mode:	>10 M
Resolution:	1 Relative unit
Bandwidth:	DC-3 Hz
Zero temperature drift (electronics only):	<.1 Relative unit/deg C
Leakage Current	<10 µA at 120 VAC (isolated via transducer)

RECORDER

Heart Rate Scale

	(Domestic)	(International)
Chart Width:	7 cm	8 cm
Scaling:	30 BPM/cm	20 BPM/cm
Range:	30-240 BPM	50-210 BPM

Uterine Activity Scale

Chart Width:	4 graticules
Scaling:	25 Relative units/cm
Range:	0-100 Relative units
Resolution:	1 Relative unit

Chart Drive

Speeds:	1 & 3 cm/min (Domestic) 1 & 2 cm/min (International)
Accuracy:	±2% at 3 cm/min

LINE VOLTAGE FREQUENCY AND POWER REQUIREMENTS

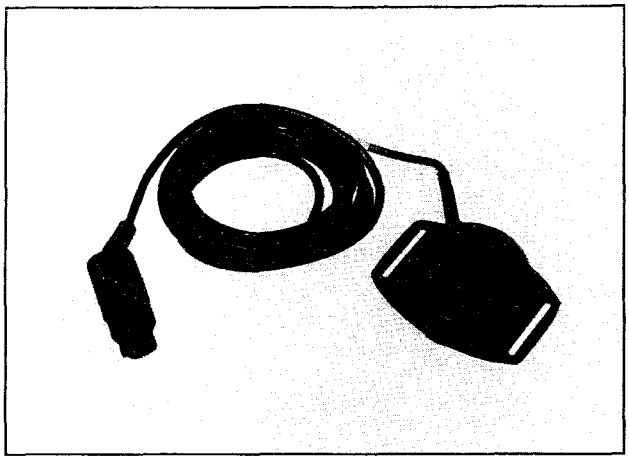
Voltage:	100-120 VAC, 220-240 VAC
Frequency:	50/60 Hz
Power Consumption:	50 Watts max.

PHYSICAL CHARACTERISTICS

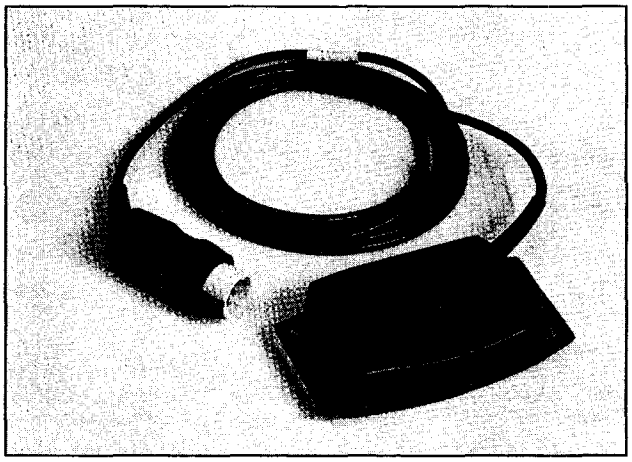
Height:	5 in. (12.7 cm)
Width:	9.75 in. (24.8 cm)
Depth:	13.4 in. (34.0 cm)
Weight:	20 lbs. (9.1 kg)

Specifications are subject to change without notice.

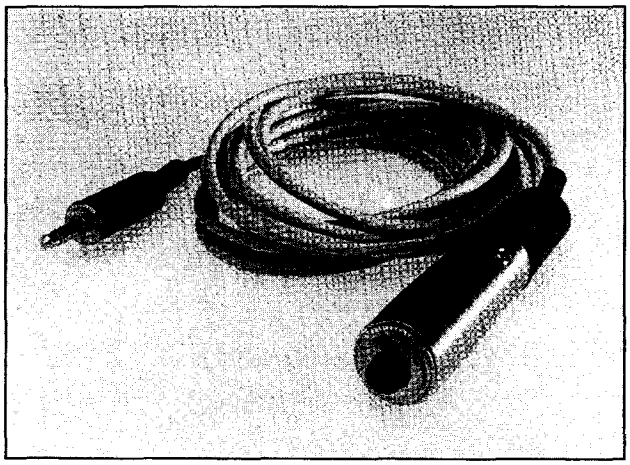
ACCESSORIES



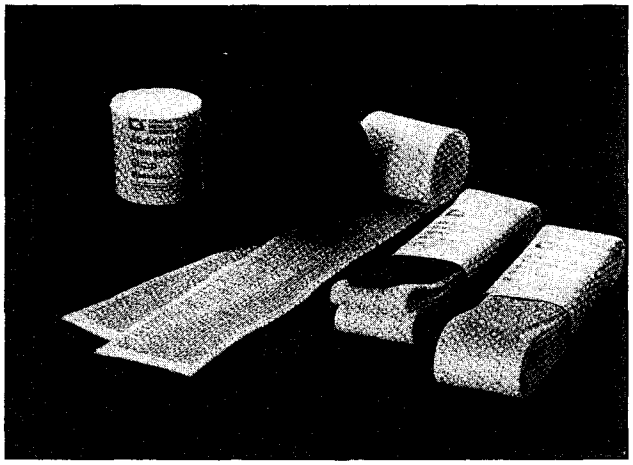
Ultrasonic Transducer, Catalog No. 5600AAX



Tocotransducer, Catalog No. 2260AAX



Remote Event Marker, Catalog No. 3919BAO



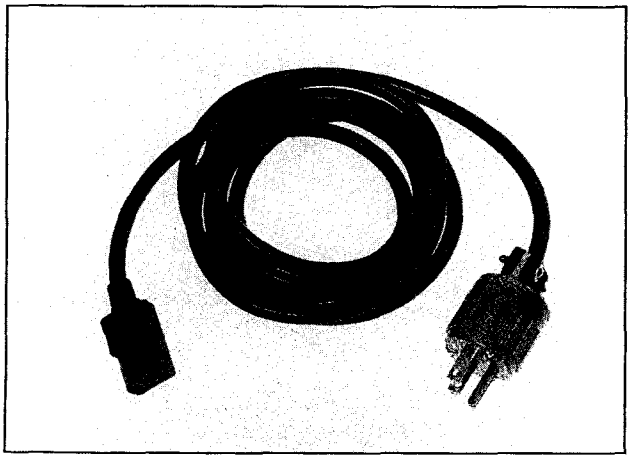
Reusable Transducer Straps, Catalog No. 4425AAO
Carton of 10 (Mesh Style)

Reusable Transducer Straps, Catalog No. 4425CAO
Carton of 10 (Velcro Style)

Disposable Transducer Straps, Catalog No. 8024AAO
Carton of 150

Model 146 Fetal Acoustic Stimulator, Catalog No. 0146AAY

Soft Carrying Case for the Model 145, Catalog No. 4484AAO



Detachable Line Cord, Catalog No. 1392AAA

Ordering Information: To order any of the accessories or supplies listed in this section call Customer Service at:
1-800-243-3952 (toll free)
In Connecticut, Call Collect 265-5631

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